



Inviz Corporation
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave., Suite 160
IRVINE CA 92612

August 14, 2023

Re: K223660
Trade/Device Name: SaintView
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 14, 2023
Received: July 14, 2023

Dear Priscilla Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K223660

Device Name
SaintView

Indications for Use (Describe)

SaintView is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specification identified by FDA. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, and medical technicians.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

(K223660)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Aug 11, 2023

1. 510K Applicant / Submitter:

Inviz Corporation
307, Biomedical Components Center,
Techno Park, 249, Chuam-ro, Buk-gu,
Gwangju, Republic of Korea

2. Submission Contact Person

LK Consulting Group USA, Inc.
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Priscilla Juhee Chung
Phone: 714.202.5789 Fax: 714-409-3357
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3. Device

- Proprietary Name: SaintView
- Common Name: Image Processing Software
- Classification: Class II (21 CFR 892.2050)
- Product Code: LLZ

4. Predicate Device

Infinitt PACS 7.0 (K172803) by Infinitt Healthcare Co., Ltd.

5. Description:

SaintView is a product for checking, analyzing, recording and storing images of medical images in hospitals. It has functions such as storing, transmitting, viewing, zooming in, reducing, moving and rotating medical images, as well as measuring length to aid in reading, and displaying various tools and reference positions. This product has a worklist for ease of reading, support for high-resolution medical monitors, and software division function for large monitors. In addition, it supports DICOM standard so that DICOM video can be checked in the viewer, and DICOM standard is also supported for video reception,

transmission, CD creation, and printing.

6. Indications for Use

SaintView is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specification identified by FDA. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, and medical technicians.

7. Substantial Equivalence Discussion:

SaintView has the same intended use and the principle of operation, and also has similar features to the predicate devices, Infinitt PACS 7.0 (K172803). There might be slight differences in features and menus, but these differences between the predicate device and the proposed device are not so significant since they do not raise any new or potential safety risks to the user or patient and questions of safety or effectiveness. Based on the results of software validation/verification tests and measurement accuracy test for angles and distances, we conclude that the proposed device is substantially equivalent to the predicate devices.

	Subject Device	Primary Predicate Device
Device Name	SaintView	Infinitt PACS 7.0
Manufacturer	Inviz Corporation	Infinitt Healthcare Co., Ltd.
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ	LLZ
Classification	Class II	Class II
Review Panel	Radiology	Radiology
510K number	K223660	K172803
Indications for Use	SaintView is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.	Infinitt PACS 7.0™, is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be

	Mammographic images may only be interpreted using a monitor that meets technical specification identified by FDA. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, and medical technicians.	interpreted using a monitor that meets technical specification identified by FDA. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, and medical technicians.
Operation System	Microsoft Windows 8/10	Microsoft Windows 7, 8.1, 10
32 bit / 64 bit	32 / 64 bit	32 / 64 bit
Image format	DICOM	DICOM
General Description	<p>SaintView is a product for checking, analyzing, recording diagnosis and storing images of medical images generated for diagnosis in hospitals. It has functions such as storing, transmitting, viewing, zooming in, reducing, moving and rotating medical images, as well as measuring length to aid in reading, and displaying various tools and reference positions. This product has a worklist for ease of reading, support for high-resolution medical monitors, and software division function for large monitors. In addition, it supports DICOM standard so that DICOM video can be checked in the viewer, and DICOM standard is also supported for video reception, transmission, CD creation, and printing.</p>	<p>Infinitt PACS 7.0™ device is PACS software capable of viewing and handling DICOM 3.x medical images. The System allows displaying of images and image studies that may not in the location as the modality. With its Web features, it is possible to review, modify, and approve studies located in a remote server. INFINITT PACS is a software device that does not contact the patient, nor does it control any life sustaining devices. The software does not provide any diagnostic assistance to the physician. Any diagnostic determination or treatment is solely determined by a 510(k) Summary of Safety and Effectiveness Infinitt PACS 7.0™ 2 physician and not the software. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed and printed.</p> <p>Infinitt PACS 7.0 is a web-based, 3D-enabled DICOM view station running on Windows 7/8.1/10. Infinitt PACS 7.0 is an integral component of INFINITT's complete INFINITT PACS/RIS solution. Infinitt PACS 7.0 fully supports DICOM standards and such functions as advanced DICOM viewing, Hanging Protocol, various 3D display such as MPR, Volume Rendering, MIP and fusion. Infinitt PACS 7.0 allows users to take full advantage of the radiographic images from various modalities in order to obtain invaluable mission critical diagnostic data and images. With Infinitt PACS 7.0, users can access their own diagnostic environment anywhere, anytime. This is made possible because Infinitt PACS 7.0 is deployed through a network and supports hanging protocol. Also, Infinitt PACS 7.0 uses JPEG 2000 features so that it takes less time to transfer images through a network. Infinitt PACS 7.0 is based upon the INFINITT G3 PACS (predicate device).</p>

		The features and functions of Infinitt PACS 7.0 have similar features and functions of G3 PACS with an updated operating system due to current advances in computer technology.
DICOM	<ul style="list-style-type: none"> • DICOM JPEG compression • DICOM JPEG2K compression(Only for Import) • DICOM Multi-frame • DICOM Storage (SCP) • DICOM Storage (SCU) • DICOM DIR - FSC, FSR, FSU • DICOM Query/Retrieve (SCU) • DICOM Multi-bytes character set • DICOM Print 	<ul style="list-style-type: none"> • DICOM JPEG compression • DICOM JPEG2K compression • DICOM Security (TLS) • DICOM Multi-frame • DICOM Storage (SCU) • DICOM DIR - FSC, FSR, FSU • DICOM Query/Retrieve (SCU) • DICOM Grayscale Softcopy Presentation State (GSPS) • DICOM Key Image Note • DICOM Multi-bytes character set • DICOM Print
Cybersecurity	<ul style="list-style-type: none"> • Access control and authentication • Multiple access prohibited • Do not hardcode passwords • No password disclosure • Ensuring the integrity of firmware or software updaters • Integrity verification and response to major executable and configuration files • Provides information on countermeasures to be taken when detecting cybersecurity threats 	<ul style="list-style-type: none"> • Supports secured network protocol • Supports auto log off • Supports audit logging • Restricting user behavior based on user roles and the institutional policies
Worklist		
Worklist	<p>General</p> <ul style="list-style-type: none"> • Supports various worklist mode <ul style="list-style-type: none"> ■ Study list ■ Favorite folder ■ DICOM QR ■ DICOM DIR ■ Case ■ Technician worklist ■ Viewed history • Supports short cut button for the specific folders of each worklist mode (Quick access) • Support open the DICOM files directly (local open) <p>Study list</p> <ul style="list-style-type: none"> • Searches the exams that meet the multiple search conditions • Configurable fetching count for the exams. • Exam list displays various information describing the exams. • Add, delete, change position and sort of each information with header column control 	<p>General</p> <ul style="list-style-type: none"> • Supports various worklist mode <ul style="list-style-type: none"> ■ Study list ■ Favorite folder ■ DICOM QR ■ DICOM DIR ■ Case ■ Conference ■ Technician worklist ■ Embedded web browser ■ Viewed history • Supports short cut button for the specific folders of each worklist mode (Quick access) • Support open the DICOM files directly (local open) <p>Study list</p> <ul style="list-style-type: none"> • Searches the exams that meet the multiple search conditions • Configurable fetching count for the exams. • Exam list displays various information describing the exams. • Add, delete, change position and sort of each information with header column control

	<ul style="list-style-type: none"> • Supports refreshing the exam list automatically by user configuration • Supports create/edit/delete search folders that contains the predefined search conditions • Exam list are configurable – font name, size, color • Changes exam status using hospital specific terminology • information using External link • Opens an exam or multiple exams in one click • Opens only key images in the selected exam • Scans documents and attaches to the selected exam • Limit data access (Passcode Rule, Hiding rule, Folder Lock) • Supports creating and view the comments of the study for private-use or sharing with specified user level. • Assigns the priority of the study • Assigns the referring doctor of the study • Assigns the Radiologist (Read doctor) of the study • Creates and shows technician note • Searches the historical exams of the selected exam • Creates and shows the report of the selected exam <p>Favorite folder</p> <ul style="list-style-type: none"> • Creates, edits and deletes the folder that are containing the interesting exams. • Adds interesting exam to specified folder by mouse dragging from Study list or creating snapshot for favorite folder. • Also, supports common functions for exam in Study list <p>DICOM QR</p> <ul style="list-style-type: none"> • Supports the list of exams retrieved by DICOM query from DICOM compatible station. • Supports send the selected exam to other station. 	<ul style="list-style-type: none"> • Supports refreshing the exam list automatically by user configuration • Exports the list of the selected exams to text file or MS Excel compatible file (CSV) • Supports create/edit/delete search folders that contains the predefined search conditions • Caches the images to the local disk with On-Call function • Exam list are configurable – font name, size, color • Changes exam status using hospital specific terminology • Launches the 3rd party application or web URL with selected exam information using External link • Opens an exam or multiple exams in one click • Opens only key images in the selected exam • Scans documents and attaches to the selected exam • Limit data access (Passcode Rule, Hiding rule, Folder Lock) • Supports creating and view the comments of the study for private-use or sharing with specified user level. • Assigns the priority of the study • Assigns the referring doctor of the study • Assigns the Radiologist (Read doctor) of the study • Creates and shows technician note • Creates and shows ER note • Searches the historical exams of the selected exam • Creates and shows the report of the selected exam <p>Favorite folder</p> <ul style="list-style-type: none"> • Creates, edits and deletes the folder that are containing the interesting exams. • Supports sharing with another user • Adds interesting exam to specified folder by mouse dragging from Study list or creating snapshot for favorite folder. • Also, supports common functions for exam in Study list <p>DICOM QR</p> <ul style="list-style-type: none"> • Supports the list of exams retrieved by DICOM query from DICOM compatible station. • Supports send the selected exam to other station.
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	<p>DICOM DIR</p> <ul style="list-style-type: none"> • Supports the list of exams in DICOM DIR • Supports displaying the exam or sending it to other station. <p>Case</p> <ul style="list-style-type: none"> • Creates, edits and deletes the folder and case that are containing the interesting images <p>Technician worklist</p> <ul style="list-style-type: none"> • Searches order and exam List • Matches or un-matches the selected order and exams • Merges or un-merges the exam • Splits the series from the exam to new one • Modifies the information of the exam or the series <p>Dash Board</p> <ul style="list-style-type: none"> • Queries the number of exams that are met the specified condition • Shows the study list that are met the specified conditions Notification 	<p>DICOM DIR</p> <ul style="list-style-type: none"> • Supports the list of exams in DICOM DIR • Supports displaying the exam or sending it to other station. <p>Case</p> <ul style="list-style-type: none"> • Creates, edits and deletes the folder and case that are containing the interesting images • Supports sharing with another user <p>Conference</p> <ul style="list-style-type: none"> • Creates, Modifies and Deletes the folder of specified conference and make a schedule of it • Adds or deletes the exams for specified conference schedule • Opens conference exam with or without snapshot • Copies or moves the exams to next conference schedule • Create and view the note (minutes) of the conference <p>Technician worklist</p> <ul style="list-style-type: none"> • Searches order and exam List • Matches or un-matches the selected order and exams • Merges or un-merges the exam • Splits the series from the exam to new one • Modifies the information of the exam or the series <p>Embedded web browser</p> <ul style="list-style-type: none"> • Browses the web pages with predefined web URL <p>Dash Board</p> <ul style="list-style-type: none"> • Queries the number of exams that are met the specified condition • Shows the study list that are met the specified conditions Notification • Notices predefined schedules or events to PACS user. <p>Notification</p> <ul style="list-style-type: none"> • Notices predefined schedules or events to PACS user.
<p>General Viewing</p>	<ul style="list-style-type: none"> • Supports image arrangement and manipulation using toolbar buttons, shortcut keys or screen shortcut • Support user-configurable mouse button action • Configures the initial settings for each specific modality • Export or convert the displayed images as DICOM or general image formats 	<ul style="list-style-type: none"> • Displays the DICOM images which are stored in PACS storage • Accesses historical exams and report : Timeline, Exam list • Supports image arrangement and manipulation using toolbar buttons, shortcut keys or screen shortcut • Support user-configurable mouse button action • Configures the initial settings for each specific modality

		<ul style="list-style-type: none"> • Supports job saving • Export or convert the displayed images as DICOM or general image formats
Toolbar	<p>Common tools</p> <ul style="list-style-type: none"> • Select • Pan • Zoom • Windowing • Magnification • Fit • Reset • Print: Report / Film • Hide demographic information • Apply previous / next HP sequence • Specific zoom: 100%, 1:1 Display (Monitor screen) Annotation • Display DICOM information tool • Monitor cine controller • Save • About <p>Annotation / Measurement tools</p> <p>Image Display Etc tools</p> <ul style="list-style-type: none"> • Display DICOM information tool • Monitor cine controller • Save • Call case folder • External link • About 	<p>Common tools</p> <ul style="list-style-type: none"> • Select • Pan • Zoom • Windowing • Magnification • Fit • Capture • Reset • Print: Report / Film • 3D cursor • Exam Refresh • Dictation (play, record) • Set as tape dictated • Hide demographic information • Save snapshot • Apply previous / next HP sequence • Specific zoom: 100%, 1:1 Display (Monitor screen) Annotation / Measurement tools Image Display 3D Tools Etc tools • Display DICOM information tool • Monitor cine controller • Save • Call case folder • External link • About <p>Annotation / Measurement tools</p> <p>Image Display 3D Tools</p> <p>Etc tools</p> <ul style="list-style-type: none"> • Display DICOM information tool • Monitor cine controller • Save • Call case folder • External link • About
Thumbnail	<ul style="list-style-type: none"> • Thumbnail display: series, image • Displays series number and how many images are in specific series • Displays an icon about the property of the series: Only one image in series, Multiple images in series, Multi-frame image in series 	<ul style="list-style-type: none"> • Thumbnail display: series, image • Displays series number and how many images are in specific series • Displays an icon about the property of the series: Only one image in series, Multiple images in series, Multi-frame image in series • Supports opening the series or image by drag and drop the thumbnail or click it
Layout	<ul style="list-style-type: none"> • Supports displaying multiple exams in a monitor by image set layout • Supports displaying multiple series or images in the image set by cell layout 	<ul style="list-style-type: none"> • Supports monitor merge • Supports displaying multiple exams in a monitor by image set layout • Supports displaying multiple series or images in the image set by cell layout

Visual Timeline	<ul style="list-style-type: none"> • Displays the information of the patients that are opened • Displays the list of all historical exams or relevant exams only for specific patient • Displays the report text of the specific historical exam 	<ul style="list-style-type: none"> • Displays the information of the patients that are opened • Displays the list of all historical exams or relevant exams only for specific patient • Displays the report text of the specific historical exam • Displays the series thumbnails of the specific historical exam • Displays jobs and snapshots in this area when creating it. (Job container)
Advanced Hanging Protocol	<ul style="list-style-type: none"> • Applies the user configurable hanging protocol for each type of exam when it is opened • Support tools for managing user hanging protocols: Create / Copy / Export / Import / Copy from another user / Delete / Search • Support user configuration for below settings in a hanging protocol • Support multiple layout sequences in a hanging protocol (hanging protocol layout group) 	<ul style="list-style-type: none"> • Applies the user configurable hanging protocol for each type of exam when it is opened • Support tools for managing user hanging protocols: Create / Copy / Export / Import / Copy from another user / Delete / Search • Support user configuration for below settings in a hanging protocol • Support multiple layout sequences in a hanging protocol (hanging protocol layout group)
Image Display		
Common	<ul style="list-style-type: none"> • Support split monitor display • Support Hanging Protocol display • Support Multi monitor display • Maximize and restore displayed image • Support easy compare mode. • Support crosslink among the series in same study • Support linked scrolling among the exams, even for difference exams • Support linked scrolling by manual-selection • Sets as key image 	<ul style="list-style-type: none"> • Support display mode: Stack / Image / Preset (VR / MPR / MIP / Web URL / Report) • Maximize and restore displayed image • Support crosslink among the series in same study • Support linked scrolling among the exams, even for difference exams • Support linked scrolling by manual-selection • Support monitor cine control for stack mode • Sets as key image • Rearranges the images by image information (Sort): image time/number/echo time/image position • Supports sequence display (Position/Time) for specific data
Output		
Print	<p>General</p> <ul style="list-style-type: none"> • Prints the images and report with paper or DICOM printer • Sends the images and report to DICOM station • Various layout adjustment • Report print with output template which is configurable for specific hospital • Selects images for printing • Prints images with or without patient information, annotations and scale bar 	<p>General</p> <ul style="list-style-type: none"> • Prints the images and report with paper or DICOM printer • Sends the images and report to DICOM station • Export the images and report to MS PowerPoint • Various layout adjustment • Report print with output template which is configurable for specific hospital • Selects images for printing • Prints images with or without patient

		information, annotations and scale bar
Report	<p>General</p> <ul style="list-style-type: none"> • Supports Built-in report module • Supports printing the text report with template Dictation <p>Text Report</p> <ul style="list-style-type: none"> • Displays the reading history who and when creates, updates and approves the report • Displays a report of historical exams of the patient and copy the text from it • Displays a predefined report template and copy the text from it (Standard report) • Supports user-defined standard report 	<p>General</p> <ul style="list-style-type: none"> • Supports Built-in report module • Support displaying the information of the reading exams • Supports Reading workflow • Supports temporally suspending the report • Supports merging the reports of multiple unread exams of a patient • Supports printing the text report with template Dictation <p>Dictation</p> <ul style="list-style-type: none"> • Stores the voice with MP3 voice file format and updates the exam status for it. • Interface with Philips Speech Mike controller Text Report <p>Text Report</p> <ul style="list-style-type: none"> • Displays the reading history who and when creates, updates and approves the report • Displays a report of historical exams of the patient and copy the text from it • Displays a predefined report template and copy the text from it (Standard report) • Supports user-defined standard report <p>Voice Recognition</p> <ul style="list-style-type: none"> • Interface with INFINITT Result (Optional) • Interface with 3rd Party VR system (Optional)

8. Performance Tests

- Measurement accuracy test for angles and distances.

We conducted performance measurements using a standardized AAPM CT phantom which is commonly employed for evaluating imaging performance in clinical settings. The subject device met the evaluation criteria below which are outlined by the AAPM CT phantom guidelines.

Category	acceptable tolerance of error rate within the measurement range for passing
Length Tapeline	Acceptable tolerance of error rate within ± 0.03 mm
Angle	Quantitative measurements aligned with the actual values
ROI	Acceptable tolerance of error rate within ± 0.01 square inches

Area	Acceptable tolerance of error rate within ± 0.01 square centimeters
Volume	Acceptable tolerance of error rate within ± 0.15 mm ³

- SW Validation

9. Conclusions:

Based on the testing performed and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate device.